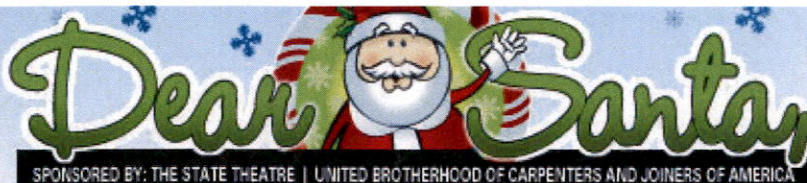


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#### PUBLIC NOTICE DATE OF THIS NOTICE: DECEMBER 28, 2011

PUBLIC NOTICE DATE OF THIS NOTICE: December 28, 2011 PURPOSE OF THIS NOTICE: The U.S. Environmental Protection Agency (EPA) is announcing its proposed decision of Corrective Action Complete without Controls under the Resource Conservation and Recovery Act (RCRA), as amended, for the B. Braun Medical, Inc. (B. Braun) facility (Facility or Site). FACILITY DESCRIPTION: The Facility is located at 901 Marcon Boulevard in Allentown, Pennsylvania. The Site occupies 29.32-acres of land in Hanover Township, Lehigh County, Pennsylvania. The property was owned by Burron Medical, Inc. from 1984 to 1994. B. Braun purchased the Site in 1994 and is the current owner. B. Braun's operations include the manufacture, preparation, and sterilization of plastic disposable medical devices, such as, valves, adapters, piercing devices, stopcocks, infusion pumps and systems, syringes, cannulae, regional anesthesia, balloon catheters, fluid administration systems, interventional products, and safety products. INFORMATION AVAILABILITY: Information regarding EPA's proposed decision is available on EPA's website at [www.epa.gov/reg3wcmd/public\\_notices.htm](http://www.epa.gov/reg3wcmd/public_notices.htm). The Administrative Record, which contains all the information considered in EPA's proposed decision, is available at U.S. EPA Region 3, 1650 Arch Street, Philadelphia, PA. 19103. Office hours are: Mon-Fri, 8:00 AM - 5:00 PM. For additional information, contact Ms. Jeanna R. Henry, Project Manager, at Mail Code: 3LC30, at EPA Region 3's address listed above; Phone: 215-814-2820; Fax: 215-814-3113, or Email: [henry.jeannar@epa.gov](mailto:henry.jeannar@epa.gov). COMMENT PROCESS: Persons wishing to comment on EPA's proposed decision must submit comments to EPA within the 30 day comment period ending January 26, 2012. Interested persons may also request a public hearing on this proposed remedy. All comments and/or requests for a hearing must be submitted in writing via mail, fax, or email to the EPA Project Manager, Ms. Jeanna R. Henry, as listed above, and must be received prior to January 26, 2012. All comments will be considered in making a final decision. FINAL DECISION: EPA will make a final decision after considering all comments, consistent with applicable RCRA requirements and regulations. If the decision is substantially unchanged from the one in this notice, EPA will issue a final decision and inform all persons who submitted written comments or requested notice of EPA's final determination. If the final decision is significantly different from the one proposed, EPA will issue a public notice explaining the new decision and will reopen the comment period.

 Appeared in: **The Express-Times** on Wednesday, 12/28/2011

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# CERTIFICATE

**B. Braun Medical Inc.**  
824 Twelfth Avenue  
Bethlehem, PA 18018 USA

Corporate Office, Servicing / Installation  
Group

**B. Braun Medical Inc.**  
901 Marcon Blvd.  
Allentown, PA 18109 USA

R&D, Manufacturing, Quality Assurance,  
Regulatory Affairs, Packaging & Distribution

**B. Braun Medical Inc**  
200 Boulder Drive  
Breinigsville, PA 18031 USA

Distribution Center

Certificate Expiry Date: October 31, 2014

Certificate Registration No: S951 01 1773

Effective Date: November 1, 2011



*G. W. Minks*

Gary W. Minks  
VP, Regulatory Affairs



Health  
Canada  
CMDCAS  
Recognized  
Registrar

## TUV®



Product Service

# CERTIFICATE

No. Q1N 09 09 44904 030

**Holder of Certificate:** B. Braun Medical Inc.  
824 Twelfth Avenue  
Bethlehem PA 18018  
USA

**Certification Mark:**



**Scope of Certificate:** Design, Development, Production, Servicing  
and Distribution of Medical Disposables  
and Subcontract Manufacturing  
Capabilities for Sterile and Non-Sterile  
Devices as listed on the attachment  
to this certificate

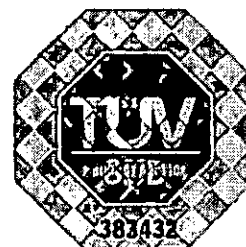
The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** DM902888

**Valid until:** 2012-09-16

**Date,** 2010-03-06

Hans-Heiner Junker



Page 1 of 2

TÜV SÜD Product Service GmbH  
Zertifizierstelle  
Ridlerstr. 65 · 80339 München  
Germany



**Akkreditiert durch**  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-999.98.12-46



Product Service

**CERTIFICATE**

**No. Q1N 09 09 44904 030**

**Applied Standard(s): EN ISO 13485:2003/AC:2007  
Medical Devices -  
Quality Management Systems -  
Requirements for Regulatory Purposes**

**Facility(ies): B. Braun Medical Inc.  
824 Twelfth Avenue, Bethlehem PA 18018,  
USA**

**B. Braun Medical, Inc.  
901 Marcon Boulevard, Allentown PA  
18109-9341, USA**

**B. Braun Medical, Inc.  
200 Boulder Drive, Breinigsville, PA 18031,  
USA**

Page 2 of 2



Thank you

Chip Marshall  
 EH&S Specialist  
 B. Braun Medical Inc.  
 HC-PM-US01  
 Phone:610-596-2934  
 Cell : 484-226-7024  
 Fax:610-266-5702  
 Email:chip.marshall@bbraun.com

Be Proactive, not Reactive: Prepare and Prevent instead of Repair and Repent

The information contained in this communication is confidential, may be attorney-client privileged, may constitute inside information, and is intended only for the use of the addressee. It is the property of B. Braun Medical Inc. or an affiliate thereof. Unauthorized use, disclosure, or copying of this communication or any part thereof is strictly prohibited and may be unlawful. If you have received this communication in error, please notify us immediately by return e-mail and destroy this communication and all copies thereof, including all attachments.

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 \*\*\*\*\*



ISO Certification

Chip.Marshall

to:

JeannaR Henry

12/09/2011 12:47 PM

Cc:

David.Lauer

Hide Details

From: Chip.Marshall@bbraun.com

To: JeannaR Henry/R3/USEPA/US@EPA

Cc: David.Lauer@bbraun.com

History: This message has been replied to.

## 2 Attachments



Cert 1.pdf Cert 2.pdf

Hi Jeanna,


I apologize in the delay in getting you the information you requested. The ISO Certification I have attached as well as the explanation you requested. The explanation came from our Corporate Regulatory Compliance Specialist.

"B. Braun Medical Inc. PA is ISO 13485:2003 registered. ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. Our FDA Establishment Registration and compliance with 21 CFR Parts 820, 210, 211, 803....allow us to sell our products within the USA. Our ISO 13485:2003 registration allows us to sell product in the European and Canadian markets (CE marked product). I am also including a copy of your ISO certs. Hope this helps."

I also checked with our Director of Quality Assurance concerning your question about the FDA. I was informed that the FDA does their routine audits every 2 years. I hope this information explains the questions you have asked. If you have any questions please do not hesitate to contact me either by E-mail or phone.

# RCRA Land Revitalization Indicators

## Status of Use & Type of Use

|                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                               | United States<br><b>ENVIRONMENTAL PROTECTION AGENCY</b><br>Region III, Philadelphia, PA                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                     |
| <b>1. Date:</b><br>August 10, 2011                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                     | WASTE MANAGEMENT<br>COUNTY _____                                                                                                                                                                                                                                                                                                                                                                                                    |                                     |
| <b>2. Facility Name</b><br>B. Braun Medical, Inc.                                                                                                                                                                                                                                                                                                                                                                                              | <b>3. EPA ID</b><br>PAD982679169                                                                                                                                                                                                                                                                                                                                                                                                    | OCT 3 2011                                                                                                                                                                                                                                                                                                                                                                                                                          |                                     |
| <b>4. Your Name</b><br>Susan R. Frund                                                                                                                                                                                                                                                                                                                                                                                                          | <b>5. Organization</b><br>Michael Baker Jr., Inc.                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                     |
| <b>6. Total Acres</b><br><u>29.32</u> acres                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                     |
| <b>Continued Use:</b><br>Total acres <u>29.32</u>                                                                                                                                                                                                                                                                                                                                                                                              | <b>Reused:</b><br>Total acres _____                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Planned Reuse:</b><br>Total acres _____                                                                                                                                                                                                                                                                                                                                                                                          | <b>Unused:</b><br>Total acres _____ |
| <b>Types of Use</b><br><input type="checkbox"/> Agricultural<br><input type="checkbox"/> Commercial<br><input type="checkbox"/> Ecological<br><input checked="" type="checkbox"/> Industrial<br><input type="checkbox"/> Military<br><input type="checkbox"/> Other Federal<br><input type="checkbox"/> Public Services<br><input type="checkbox"/> Recreational<br><input type="checkbox"/> Residential<br><input type="checkbox"/> Mixed Use | <b>Types of Use</b><br><input type="checkbox"/> Agricultural<br><input type="checkbox"/> Commercial<br><input type="checkbox"/> Ecological<br><input type="checkbox"/> Industrial<br><input type="checkbox"/> Military<br><input type="checkbox"/> Other Federal<br><input type="checkbox"/> Public Services<br><input type="checkbox"/> Recreational<br><input type="checkbox"/> Residential<br><input type="checkbox"/> Mixed Use | <b>Types of Use</b><br><input type="checkbox"/> Agricultural<br><input type="checkbox"/> Commercial<br><input type="checkbox"/> Ecological<br><input type="checkbox"/> Industrial<br><input type="checkbox"/> Military<br><input type="checkbox"/> Other Federal<br><input type="checkbox"/> Public Services<br><input type="checkbox"/> Recreational<br><input type="checkbox"/> Residential<br><input type="checkbox"/> Mixed Use |                                     |

**Unit Conversions:** 1 square foot = 0.000023 acre; 1 square meter = 0.0002471 acre

## **Current Land Use**

**Continued Use** - A site or portion of a site which is currently being used in the same general manner as it was when the site became contaminated. For example, continued use would be an appropriate description for a property where industrial operations resulted in the contamination and the property is still used as an operating industrial facility. The RCRA Program will count all acres of an active RCRA industrial facility as Continued Use, except for parcels specifically designated as Reused or Planned Reuse.

**Reused** - A site or portion of a site where a new use, or uses, is occurring such that there has been a change in the type of use (e.g. industrial to commercial) or the property was vacant and now supports a specific use. This means that the developed site, or portion of the site, is "open" or actually being used by customers, visitors, employees, residents, etc.

**Planned Reuse** - A site or portion of a site where a plan for new use is in place. This could include conceptual plans, a contract with a developer, secured financing, approval by the local government, or the initiation of site redevelopment.

**Unused** - A site or portion of a site that is currently vacant or not being used in any identifiable manner. This could be because site investigation and cleanup are on-going, operations ceased or owner is in bankruptcy, or cleanup is complete but the site remains vacant.

## **Types of Use**

**Commercial Use** – Commercial use refers to use for retail shops, grocery stores, offices, restaurants and other businesses.

**Public Service Use** – Public service use refers use by a local or state government agency or a non-profit group to serve citizens' needs. This can include transportation services such as rail lines and bus depots, libraries and schools, government offices, public infrastructure such as roads, bridges, utilities or other services for the general public.

**Agricultural Use** – Agricultural uses refers to use for agricultural purposes, such as farmland for growing crops and pasture for livestock. It also can encompass other activities, such as orchards, agricultural research and development, and irrigating existing farmland.

**Recreational Use** – Recreational use refers to use for recreational activities, such as sports facilities, golf courses, ball fields, open space for hiking and picnicking, and other opportunities for indoor or outdoor leisure activities.

**Ecological Use** – Ecological use refers to areas where proactive measures, including a conservation easement, have been implemented to create, restore, protect or enhance a habitat for terrestrial and/or aquatic plants and animals, such as wildlife sanctuaries, nature preserves, meadows, and wetlands.

**Industrial Use** – Industrial use refers to traditional light and heavy industrial uses, such as processing and manufacturing products from raw materials, as well as fabrication, assembly, treatment, and packaging of finished products. Examples of industrial uses include factories, power plants, warehouses, waste disposal sites, landfill operations, and salvage yards.

**Military Use** – Military use refers to use for training, operations, research and development, weapons testing, range activities, logistical support, and/or provision of services to support military or national security purposes.

**Other Federal Use** – Other federal use refers to use to support the Federal government in federal agency operations, training, research, and/or provision of services for purposes other than national security or military.

**Mixed Use** – Mixed use refers to areas at which uses cannot be differentiated on the basis of acres. For example, a condominium with retail shops on the ground floor and residential use on the upper floors would fall into this category.

**Residential Use** – Residential use refers to use for residential purposes, including single-family homes, town homes, apartment complexes and condominiums, and child/elder care facilities.



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B BRAUN MEDICAL INC

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PAD982679169

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|--------|---------|-------------------------|-----------------|----------------|-------------|------|--------------------------------------------------------------------------|-------------|----------------------------------|-------|----------------------------|
| Seq.   | Act Loc | Event Code              | Sched Date Orig | Sched Date New | Actual Date | Agcy | Description                                                              | Count       |                                  | Count |                            |
| 1      | PA      | <a href="#">CA800YE</a> |                 |                | 02/01/2012  | E    | READY FOR ANTICIPATED USE DETERMINATION - READY FOR ANTICIPATED USE      | 1           | <a href="#">Show Authorities</a> | 1     | <a href="#">Show Areas</a> |
| 1      | PA      | <a href="#">CA999NF</a> |                 |                | 02/01/2012  | E    | CA PROCESS IS TERMINATED-NO FURTHER ACTION                               | 1           | <a href="#">Show Authorities</a> | 1     | <a href="#">Show Areas</a> |
| 1      | PA      | <a href="#">CA550NR</a> |                 |                | 02/01/2012  | E    | REMEDY CONSTRUCTION-NO REMEDY CONSTRUCTED                                | 1           | <a href="#">Show Authorities</a> | 1     | <a href="#">Show Areas</a> |
| 1      | PA      | <a href="#">CA900NC</a> |                 |                | 02/01/2012  | E    | CA PERFORMANCE STANDARDS ATTAINED - NO CONTROLS NECESSARY                | 1           | <a href="#">Show Authorities</a> | 1     | <a href="#">Show Areas</a> |
| 1      | PA      | <a href="#">CA725YE</a> |                 |                | 12/01/2011  | E    | HUMAN EXPOSURES CONTROLLED DETERMINATION-YES, APPLICABLE AS OF THIS DATE | 1           | <a href="#">Show Authorities</a> | 1     | <a href="#">Show Areas</a> |
| 1      | PA      | <a href="#">CA750YE</a> |                 |                | 12/01/2011  | E    | RELEASE TO GW CONTROLLED DETERMINATION-YES, APPLICABLE AS OF THIS DATE   | 1           | <a href="#">Show Authorities</a> | 1     | <a href="#">Show Areas</a> |
| 1      | PA      | <a href="#">CA100</a>   |                 |                | 05/02/2011  | E    | INVESTIGATION IMPOSITION                                                 | 1           | <a href="#">Show Authorities</a> | 1     | <a href="#">Show Areas</a> |

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## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

OCT 3 2011

## Primary Screening – Question #1

**Q1:** Are chemicals of sufficient volatility and toxicity (Table 1) known or reasonably suspected to be present in subsurface soils, soil gas, or ground water; the presence of these chemicals having resulted from releases subject to RCRA Corrective Action (e.g., from Solid Waste Management Units (SWMU), Regulated Units (RU), or Areas of Concern (AOC))?

\_\_\_\_\_ If YES - check here, check the relevant chemicals on Table 1, and continue with Question 2 below;

X If NO - check here, provide rationale and references below, and skip to the Pathway-Specific EI Summary Page and document that the subsurface vapor to indoor air pathway is incomplete; or

\_\_\_\_\_ If sufficient data are not available, skip to the Pathway-Specific EI Summary Page and enter "IN" (more information needed) status code.

**Criteria:**

Table 1 provides a list of chemicals and indicates whether they are sufficiently volatile and toxic to pose an incremental lifetime cancer risk greater than  $10^{-5}$  or a hazard index (HI) greater than 1, assuming continuous exposure to the maximum possible vapor concentration. This is an extremely conservative criterion, corresponding to an infinite supply of the pure chemical (e.g., NAPL pool), and no indoor air dilution, which is highly unlikely to occur. The exposure assumptions and calculations are documented in Appendix B.

Note: Table 1 may not include all possible chemicals of concern; it can be revised to include other chemicals according to the methods described in Appendix B, if the necessary chemical property and toxicity data is available.

**Rationale and References:**

**B. Braun Medical, Inc. (B. Braun)**, a privately-owned health care company, provides healthcare products and support services in the fields of drug delivery, intravenous (IV) therapy, pain control, clinical nutrition, dialysis, and vascular intervention. The company was founded in 1957. Prior to 1991, the company operated as Burron Medical Products, Inc. The facility is situated in an industrial/office complex within the intersections of Marcon Boulevard and Postal Road with Irving Street. The property, 29.32 acres, is surrounded by office complex buildings to the immediate north, east, south and west. The facility generates wastes during the manufacturing and preparation of plastic disposable medical devices in a 360,000 square foot building at 901 Marcon Boulevard. On June 11 1990, the United States Environmental Protection Agency (USEPA) received Burron Medical Inc.'s initial Notification of Hazardous Waste Activity (PAD982679169) for the facility.

The facility generates wastes during the manufacturing and preparation of plastic disposable medical devices (there is no cleaning of medical devices; however, surface areas are wiped down to ensure cleanliness) and handled waste onsite for less than 90 days are covered under a permit-by-rule (PBR). The facility's elementary neutralization unit is located within the southern portion of the building which requires card access to the building and card access to the area of the neutralization unit. The unit consists of a 3,000-gallon aboveground storage tank (AST), two towers and a reaction tank. The entire unit is enclosed by cinder block walls on three sides and a six-inch high concrete curb on the fourth side.

The facility produces approximately 2,200 pounds of waste per month, making them a large quantity generator (LQG). Wastes identified for offsite disposal included: D001 (IPA, characteristically ignitable), D039 (tetrachloroethylene [PCE]), D008 (lead), D009 (mercury), D010 (selenium), and F002 (spent halogenated solvents including methylene chloride). As a by-product of the facility's closed-loop ethylene oxide sterilization emissions control system (deox scrubber system), the facility neutralizes the ethylene glycol process wastewater using sodium hydroxide. The neutralization waste is hazardous because of the corrosivity of the mixture (20% ethylene glycol and 80% water). The neutralized process water is transported offsite by others for ethylene glycol reuse.

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

A 4,000-gallon registered underground storage tank (UST) (Tank 001) receives ethylene glycol in the event of a spill from the floor drains throughout the area where ethylene oxide is used and from the deoxx scrubber system, and condensation from the sterilization units. The UST acts as an emergency catch basin if the manufacturing process malfunctions.

No solid waste management units (SWMUs) or areas of concern (AOCs) were identified in available documents pertaining to the facility; however, a SWMU (the Hazardous Waste Accumulation Area) was identified during a site visit that occurred on May 2, 2011. Wastes generated at the facility are stored in the hazardous waste accumulation area located on the north side of the building. Wastes generated at the facility include waste liquid solvents and solvent soaked rags used for preparation of the medical devices. The wastes generated in the laboratories and manufacturing areas are containerized in three-gallon containers or five gallon step cans. The wastes are moved nightly to a satellite storage area inside of the north corner of the facility, where they are combined into 55-gallon drums and ultimately transferred to the hazardous waste accumulation area. During the site visit, one 55-gallon drum containing solvent rags and one 55-gallon drum, Resource Conservation and Recovery Act (RCRA) empty, were observed in the satellite storage area. The hazardous waste accumulation area consists of a 10 foot by 20 foot self-contained steel modular shed that is kept locked. During the May 2, 2011 site visit, seven drums of hazardous waste and five empty, non-hazardous drums were observed inside of the shed. The shed was neat and orderly and no evidence of spills/releases was observed.

B. Braun currently operates under an active Title V air permit (permit number 39-00055) which was issued on January 13, 2010, and is effective through January 12, 2015. Emissions sources included under the permit are two boilers, four emergency generators, two fire pumps, eight sterilizers, the aeration room, the catalytic oxidizer, and the deoxx scrubber system. As discussed earlier, several NOV's were cited but later rescinded by PADEP. There have been no recorded releases to air; therefore, it is concluded that no controls are relevant for the air exposure pathway.

Additionally, there have been no known/reported releases of chemical constituents to soil or groundwater at the facility. Therefore, no further vapor intrusion evaluation or controls for the vapor intrusion pathway are required related to the facility's historical/present operations.

Therefore, considering the available information about the facility, there are no chemicals documented in soils and/or groundwater at this facility that are identified as sufficiently volatile and toxic to warrant evaluation of potential subsurface vapor to indoor air.

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

### Primary Screening – Question #2

**Q2: Are inhabited buildings located near subsurface contaminants having sufficient volatility and toxicity?**

\_\_\_\_\_ If YES - check here, identify buildings below, and continue with Question 3 below.

\_\_\_\_\_ If NO -- check here and skip to the Pathway-Specific EI Summary Page and document that the subsurface vapor to indoor air pathway is incomplete, or

\_\_\_\_\_ If sufficient data are not available - check here and skip to Pathway-Specific EI Summary Page and enter "IN" (more information needed) status code.

### Criteria:

The goal of this question is to identify buildings that could potentially have a complete pathway, i.e., indoor air concentrations above levels that would pose a lifetime incremental cancer risk of  $10^{-5}$ , or a hazard index of  $>1$ . For the purposes of this question:

- “inhabited buildings” are structures with enclosed air space that are designed for human occupancy.
- “subsurface contaminants having sufficient volatility and toxicity” are defined by Table 1 and were discussed above in Question 1.
- An inhabited building is considered “near” subsurface contaminants if it is located within 100 ft laterally of known or interpolated soil gas or groundwater concentrations in excess of the criteria in Table 2.

A distance criterion is necessary to focus the assessment on buildings most likely to have a complete pathway. Vapor concentrations generally decrease with increasing distance away from a subsurface vapor source, and at some distance, the concentrations become negligible. The distance at which concentrations are negligible is a function of the mobility, toxicity and persistence of the chemical, as well as the geometry of the source, subsurface materials, and characteristics of the building of concern. Definitive studies on this topic have yet to be conducted, but 100 feet is a reasonable criterion when considering vapor migration fundamentals, typical sampling density, and uncertainty in defining the actual contaminant spatial distribution.

### Identify Inhabited Buildings Within Distances of Possible Concern:

\_\_\_\_\_

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

### Primary Screening Stage— Question #3

Q3. Is **immediate action warranted** to mitigate current risks to residents of those buildings identified in Question 2 to be located within the area of concern?

\_\_\_\_\_ If YES – check here and proceed with immediate actions to verify or eliminate imminent risks, which may include indoor air quality monitoring, engineered containment or ventilation systems, or relocation of receptors<sup>1</sup>. The immediate action(s) should be appropriate for the situation.

\_\_\_\_\_ If NO – check here and then continue with Question 4 below.

#### Criteria:

Here we focus on those buildings identified in Question 2 to be located within the areas of concern. The following qualitative criteria are considered sufficient to justify immediate actions:

**Odors** reported by occupants, particularly if described as “chemical”, or “solvent”, or “gasoline”. The presence of odors does not necessarily correspond to adverse health and/or safety impacts and the odors could be the result of indoor vapor sources; however, it is prudent to investigate any reports of odors as the odor threshold for some chemicals exceeds their respective acceptable target breathing zone concentrations.

**Physiological effects** reported by occupants (dizziness, nausea, vomiting, confusion, etc.).

**Wet basements**, in areas where chemicals of sufficient volatility and toxicity (see Table 1) are known to be present in groundwater and the water table is shallow enough that the basements are prone to groundwater intrusion or flooding, especially if there is evidence of light, non-aqueous phase liquids (LNAPLs) floating on the water table directly below the building, and/or any direct evidence of contamination (liquid chemical or dissolved in water) inside the building.

**Short-term safety concerns** are known, or are reasonably suspected to exist - for example: a) explosive or acutely toxic concentrations of vapors have been measured in the building or connected utility conduits; b) explosive or acutely toxic levels of vapors are likely to be present in utility conduits, sumps, or other subsurface drains directly connected to the building. Lower explosive limits are typically in the range of 1 to 5% by volume (10,000,000 ppbv to 50,000,000 ppbv).

There may be circumstances in which the Responsible Party elects to initiate indoor air quality monitoring and/or proactively eliminate exposures through avoidance or mechanical systems, rather than pursue continued assessment of the pathway. In some cases this may be a cost-effective option as it leads directly to an incomplete subsurface vapor to indoor air pathway. This option is available at any time in the assessment. Furthermore, some buildings are positively pressurized as an inherent design of the heating, ventilating and air conditioning system, and it may be possible to show that the pathway is incomplete by demonstrating a significant pressure differential from the building to the subsurface. Proactive indoor air quality monitoring may also be initiated at any time, although it is not necessary if the pathway can be confirmed to be incomplete using other data.

#### Rationale and Reference(s): -

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

Q4: Do measured or reasonably estimated indoor air, soil gas, or ground water concentrations<sup>2</sup> exceed the target media-specific concentrations given in Table 2?

\_\_\_\_\_ If NO, and there is no reason to believe that the conservative attenuation factor of 0.01 is inappropriate—document representative media concentrations on Table 2 and check here. Go to the Pathway-Specific EI Summary Page and document that the subsurface vapor to indoor air pathway is incomplete.

\_\_\_\_\_ If YES – check here. If indoor air concentrations are known and these are greater than the target indoor air concentrations, then the pathway is complete and engineering controls or avoidance measures need to be implemented. If only soil gas or groundwater data are available, and these exceed the target criteria, document representative media concentrations on Table 2 and then proceed to Question 5.

\_\_\_\_\_ If sufficient data are not available - check here and skip to Pathway-Specific EI Summary Page and enter “IN” (more information needed) status code.

### Criteria:

Question 4 is intended to allow a rapid screening of available site data, which may include soil gas, groundwater, or indoor air concentrations. Concentrations in the three media are assumed to be correlated, so that data from any of the three media can be used. If data are available for more than one media, all of the data should be considered in answering Question 4. As discussed in Appendix A, confidence in the assessment increases with multiple lines of evidence, so additional data may be collected for consideration in Question 4, at the discretion of either the responsible party or the lead regulatory authority, to the extent that this may be necessary and appropriate.

Note that it is important to segregate the buildings of interest into two categories: a) buildings lying above areas where contaminated groundwater is the only source of contaminant vapors, and b) buildings lying above areas where contaminated vadose (unsaturated) zone vapor sources are present. While indoor air quality data can be used to judge the pathway completeness in either case, the appropriate use of groundwater and soil gas data is different for these two cases. In case (a) either the soil gas or groundwater criteria in Table 2 can be used at this step, while in case (b) only soil gas criteria and soil gas samples collected above the vapor source zone can be used. This is because the groundwater criteria have been derived assuming no other vapor sources between the water table and the building foundation. This also applies for Question 5.

The term “measured or reasonably estimated” is used above (and throughout this document) as it is recognized that measurements at all buildings of concern may not be practical or necessary. For example, groundwater concentrations beneath buildings are commonly estimated from concentrations collected in wells distributed about a larger area of interest. Likewise, one might reasonably estimate upper bound indoor air concentrations for a group of buildings based on the measurements taken from those buildings expected to have the highest concentrations.

In the case of soil gas concentrations, measured or reasonably estimated soil gas concentrations at any depth in the subsurface may be used in Question 4, provided that this depth falls below the foundation depth. As there are concerns about the integrity of shallow soil gas samples, it is recommended that samples collected at depths <5 ft below ground surface (BGS) not be used for this analysis, unless they are collected immediately below the building foundation several feet in from the edge. Samples from fixed probes are also preferable, but not required. With respect to the spatial distribution of sampling points, close proximity to the building(s) of concern is preferred; however, it may be possible to reasonably estimate concentrations based on data from soil gas samples collected about a larger area. Users should also consider that, in general, samples collected at depth closer to the vapor source are much less likely to be dependent on the surface cover (i.e. pavement, lawn, foundation) than shallow soil gas samples.

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

In the case of groundwater concentrations, these should be measured or reasonably estimated using samples collected from wells screened at, or across the top of the water table. This is necessary to be consistent with the derivation of the target groundwater criteria in Table 2. Samples from groundwater monitoring wells may be a blend of groundwater from different levels across the screened interval. Confidence in the results can be increased through use of a more narrowly screened interval across the water table, or a variety of other depth-discrete sampling protocols. These issues, and others to be considered during data collection, are discussed in Appendix A.

Question 4 calls for comparison with the target criteria given in Table 2; however, this guidance is not intended to supersede existing state-specific guidance or regulations. Thus, the lead regulatory agency will determine the appropriate criteria to be used here and in Questions 5 and 6. If target criteria are not available, then the tables provided with this guidance should be used. A regulatory agency may have already developed acceptable indoor air concentrations, but they might not have derived vapor intrusion pathway-specific target media concentrations. In this case, the methods discussed in Appendix B can still be used to derive target soil gas and dissolved groundwater concentrations consistent with those existing target indoor air concentrations. Where pathway-specific media concentrations already exist, the values provided in this guidance should be considered national benchmarks, and the governing regulatory authority should compare the methods and assumptions used to derive their criteria with the methods used in this guidance. In any case, users of this guidance should review the methods used to derive the tables presented in this guidance, and consider whether or not the assumptions and methods are appropriate for their application. These assumptions are discussed briefly below, and in more detail in Appendix B.

The target media-specific concentrations given in Table 2 correspond to indoor air concentrations calculated to cause an incremental lifetime cancer risk of  $10^{-5}$  or a Hazard Index of 1.0 (whichever is more restrictive). In the case of the soil gas criteria, a conservative soil gas to indoor air attenuation factor of 0.01 is used. For the groundwater criteria, there is an additional conservative assumption that the partitioning of chemicals between groundwater and soil vapor is assumed to obey Henry's Law. Table 2 may not include all possible chemicals of concern; it can be revised to include other chemicals of concern according to the methods described in Appendix B, if chemical property and toxicity data is available.

The soil gas to indoor air attenuation factor represents the ratio of the indoor air concentration to the soil gas concentration at some depth. The 0.01 value is considered to be a reasonable upper-bound value for the case where the soil gas concentration immediately beneath a foundation is used (e.g., the indoor air concentration would not be expected to exceed 1/100 of the concentration immediately below the foundation). This value is based on available data from sites where paired indoor air and soil gas samples immediately below a foundation were available, and also theoretical considerations. It is a conservative enough criterion that it should be protective even in settings where the building has significant openings to the subsurface. In addition, since it has been argued that the 0.01 value is conservative for deriving near foundation soil gas criteria, the soil gas criteria derived using this value would be even more conservative if applied to soil gas concentrations measured or reasonably estimated at any other deeper depth. For reference, attenuation factors as low as 0.00001 have been determined from data at some sites. There may be some settings where the 0.01 attenuation factor is not a conservative upper-bound value; however, most of these settings would presumably be identified and addressed in Question #3.

The authors of this guidance felt that the uncertainties associated with soil partitioning calculations as well as the uncertainties associated with soil sampling and soil chemical analyses (see EPA/600/SR-93/140) were so great that use of soil concentrations for assessment of this pathway is not technically defensible. Thus, soil concentration criteria were not derived and the use of soil criteria is not encouraged. However, as discussed above, this guidance is not intended to supersede existing State guidance, and users should follow the appropriate guidance as determined by the lead regulatory authority. Furthermore, proponents may elect to defend the use of soil concentration data in the Site-Specific Pathway Assessment, Question 6.

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

The soil gas and groundwater target concentrations were derived from the target indoor air criteria, without consideration of ambient outdoor air quality or other chemical sources internal to the building. The target concentrations should therefore be interpreted as target incremental concentrations above background levels. To be consistent with that definition, background concentrations should be subtracted from measured or reasonably estimated indoor air concentrations before comparison against the Table 2 (or other appropriate) criteria.

Values appearing in Table 2 were derived for an incremental lifetime cancer risk (R) of  $1 \times 10^{-5}$  and hazard index (HI) of 1. The risk-manager or decision-maker should consider a number of variables when comparing site data to the Table 2 criteria, including: the number and locations of samples, the spatial and temporal variability of concentrations, the frequencies of exceedances of Table 2 criteria, the magnitude of exceedances of Table 2 criteria, and the degree of conservatism built into Table 2 values. The Table 2 criteria are not intended for use as "bright-line criteria", below which any measured or reasonably estimated concentrations are acceptable and above which any concentrations are unacceptable. Instead, professional judgment should be used when applying the criteria. For example, if eight out of ten samples satisfy Table 2 criteria and the other two exceed the criteria, but only by a factor of two or three, the risk-manager might decide that the pathway is incomplete, even though two of the samples exceed the criteria. This is because the risk estimate is still in the same order-of-magnitude as the target risk level and there is some conservatism built into the Table 2 values.

### **Rationale and Reference(s):**

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

### Secondary Screening – Question #5

Q5: Using the appropriate scenario-specific attenuation factor (from Figure 1), do measured or reasonably estimated soil gas or ground water concentrations exceed the target media-specific concentrations given in Table 3?

\_\_\_\_\_ If NO, and there is no reason to believe that the scenario-specific attenuation factor is inappropriate, check here and document the Rationale and References for the scenario-specific attenuation coefficient below. Go to the Pathway-Specific EI Summary Page and document that the subsurface vapor to indoor air pathway is incomplete.

\_\_\_\_\_ If YES – check here, and if representative measured or reasonably estimated soil gas and/or groundwater concentrations are considerably (i.e. greater than 100 times) higher than the values in Table 3 then interim exposure controls and/or measurement of indoor air quality monitoring should be conducted as soon as practicable; and when representative media concentrations are less than 100 times the appropriate Table 3 values proceed to further analysis and modeling in Question 6.

\_\_\_\_\_ If sufficient data are not available - check here and skip to Pathway-Specific EI Summary Page and enter "TN" (more information needed) status code.

#### Criteria:

Soil gas or groundwater to indoor air attenuation factors are expected to depend on building characteristics, chemical type, soil type, and depth of the source (which is defined as either a measured soil gas concentration at the specified sample collection depth below the building, or the ground water concentration at the depth of the water table). The 0.01 attenuation factor value used in Question 4 is representative of expected upper bound values for vapors located immediately below the building, and therefore does not depend on soil type or depth. Question 5 considers the site-specific soil type and depth of source to allow for a more representative vapor attenuation factor, and consequently the target media concentrations. The target indoor air concentrations remain the same (unchanged from Table 2), but target soil gas and groundwater concentrations will vary with changes in the vapor attenuation factor.

Attenuation factors have been calculated for some combinations of source depth, soil type, and building characteristics using the Johnson and Ettinger (1991) model. Reasonable building characteristics were selected and held constant in these calculations and the chemicals were assumed not to degrade. To capture the effect of changes in soil properties, the U.S. Soil Conservation Service (SCS) soil texture classifications were considered, and a subset of these were selected. This subset was chosen so that their relevant properties (porosity and moisture content) would collectively span the range of conditions most commonly encountered in the field. Then, plots of attenuation factor vs. depth were calculated and these results are presented below in Graphs 1a (for use of soil gas data) and 1b (for use of groundwater data). The two graphs are different because the first does not have to account for transport across the capillary fringe.

Details of these calculations are included in Appendix B. The depth used should be: a) the vertical separation between the soil gas sampling point and the building foundation for use of Graph 1a, or b) the vertical separation between groundwater and the building foundation for use of Graph 1b. Samples collected near to, but at depths shallower than the building foundation should not be used. Table 4 should be used to help select the most appropriate soil texture classification as discussed below.

The site characterization should include collection of soil samples at various depths between the building foundation elevation and contamination source (i.e., vertical soil gas and/or groundwater quality profiling) and description of soil lithology. The preferred method for determining the SCS soil class is to use lithological information combined with the results of grain size distribution tests on selected soil samples. Procedures for conducting grain size distribution tests are provided in American Society for Testing and Materials (ASTM) Standard Test Method for Particle Size Analysis of Soils (D422-63) and U.S. Natural Resources Conservation (NRCC) Soil Survey Laboratory Methods Manual, Soil Survey Laboratory Investigations Report No. 42.

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

The U.S. SCS soil texture classes are based on the proportionate distribution of sand, silt and clay sized particles in soil. It does not include any organic matter. The grain size boundaries are as follows:

Sand: 0.05 mm to 2 mm  
Silt: 0.002 mm to 0.05 mm  
Clay: <0.002 mm

The soil textural classes are displayed in the SCS soil textural triangle. The soil texture class is determined by plotting the grain size distribution results on the soil texture triangle. If a soil texture class is not intersected based on the five classes included in the guidance, the nearest soil class is chosen. The selection of the soil texture class should be biased towards the coarsest soil type of significance, as determined by the site characterization program.

There are sites where different soil classifications systems have been used, and where information on soil lithology and grain size distribution is limited. Most engineering soil classification systems are either based on grain size, or a combination of grain size and engineering properties (e.g., Unified Soil Classification System (USCS), ASTM D2488-84, NAVFAC DM7.2 (1982)). For several soil classification systems, soil is divided into a coarse-grained fraction consisting of sand and gravel (or larger) particles (greater than 0.075 mm size) and fine-grained fraction consisting of silt and clay (less than 0.075 mm size). Soils are characterized as fine-grained if more than 50 percent is less than 0.075 mm in size. Various descriptors of particle size proportions such as trace, few, little, some, or use of the grain size class as an adjective or noun are often used to describe different soil types. In some cases engineering properties are also used to determine the appropriate soil type description. Unfortunately, there are widespread differences in both the soil classification systems used to describe soils and differences in the quality of lithological descriptions incorporated in boring logs. To assist users of guidance in cases where lithological and grain size information is limited, Table 4 below provides guidance that can be used to select, in appropriate terms, the appropriate soil texture class.

Table 4. Guidance for selection of soil type curves in Graphs 1a and 1b.

| If your boring log indicates that the following materials are the predominant soil types . . .                              | then you should use the following texture classification when obtaining the attenuation factor |
|-----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>Sand or Gravel or Sand and Gravel</b> , with less than about 12% fines, where "fines" are smaller than 0.075 mm in size. | Sand                                                                                           |
| <b>Sand or Silty Sand</b> , with about 12% to 25% fines                                                                     | Loamy Sand                                                                                     |
| <b>Silty Sand</b> , with about 20% to 50% fines                                                                             | Sandy Loam                                                                                     |
| <b>Silt and Sand or Silty Sand or Clayey, Silty Sand or Sandy Silt or Clayey Sandy Silt</b> , with about 45 to 75% fines    | Loam                                                                                           |
| <b>Sandy Silt or Silt</b> , with about 50 to 85% fines                                                                      | Silt Loam                                                                                      |

We note that there is no soil texture class represented as consisting primarily of clay. Exclusion of clay was deliberate since homogenous, unfractured clay deposits are rare. Users of this guidance have the option to refine selection of soil properties as part of the Site Specific Pathway Assessment.

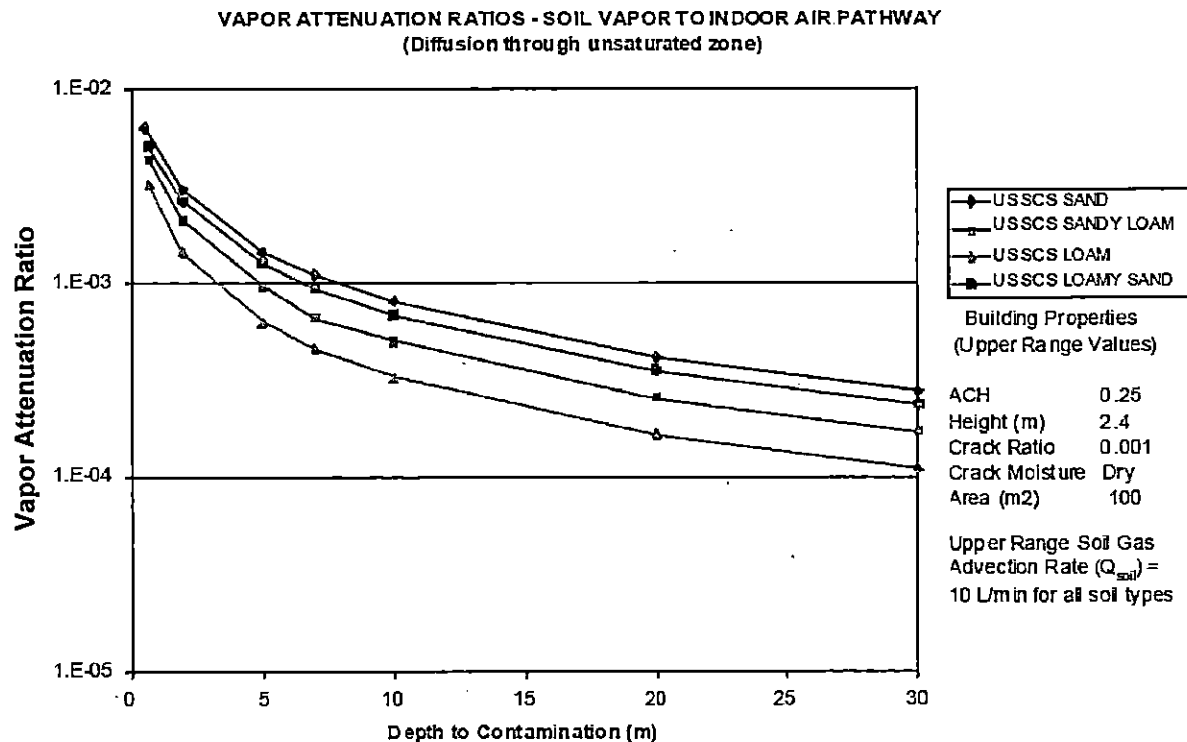
The user must defend their scenario choice with site-specific data. Given the approximate nature of this approach, users should round their attenuation factor to the nearest half order-of-magnitude (0.01, 0.003, 0.001, 0.0003, or 0.0001), selecting the higher number if the best estimate is between two increments. Then, the columns in Table 3 can be used to determine the appropriate target media concentrations. Values in Table 3 were derived as discussed in Appendix B.

Interim exposure controls and/or measurement of indoor air quality should be conducted as soon as practicable if measured or reasonably estimated soil gas and/or groundwater concentrations are considerably (i.e. greater than 100 times) higher than the values in Table 3 since the Site-Specific Assessment step is very unlikely to result in an attenuation factor that is 100 times smaller than the attenuation factor determined at this stage. This is especially true for any chemical (degradable or not) when shallow (e.g., <2 ft beneath the building foundation) soil gas concentrations are being used for assessment.

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

If the media concentrations being used are from a significant depth and the chemicals of concern are known to degrade aerobically, it is possible for the actual attenuation factor to be considerably less than the value determined in this step. However, this issue should be addressed through vertical soil gas profile sampling involving shallower samples in this question (or other direct empirical evidence and supporting data to show the profile of oxygen, carbon dioxide, or other indicators of microbial activity are adequate to validate conceptual models based on analogous case studies in similar settings, in Question 6). Again, if shallow soil gas samples are being used, it is unlikely that degradation will contribute significantly to increased attenuation between the sampling point and the building.

It should also be recognized that it may be less expensive (or more desirable for other reasons) to install and operate exposure controls than to conduct further assessment. This guidance neither requires nor precludes such an approach, and it is left to the discretion of the responsible party to decide if proactive exposure controls are cost-effective.



**FIGURE 1**

Graph 1a. For use with soil gas monitoring data.

(future edits to add: units of feet, ½ order-of-magnitude lines, and clarify y-axis is "Vapor Attenuation Ratio")

# EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

## VAPOR ATTENUATION RATIO - GROUNDWATER TO INDOOR AIR PATHWAY (Diffusion through capillary fringe & unsaturated zone)

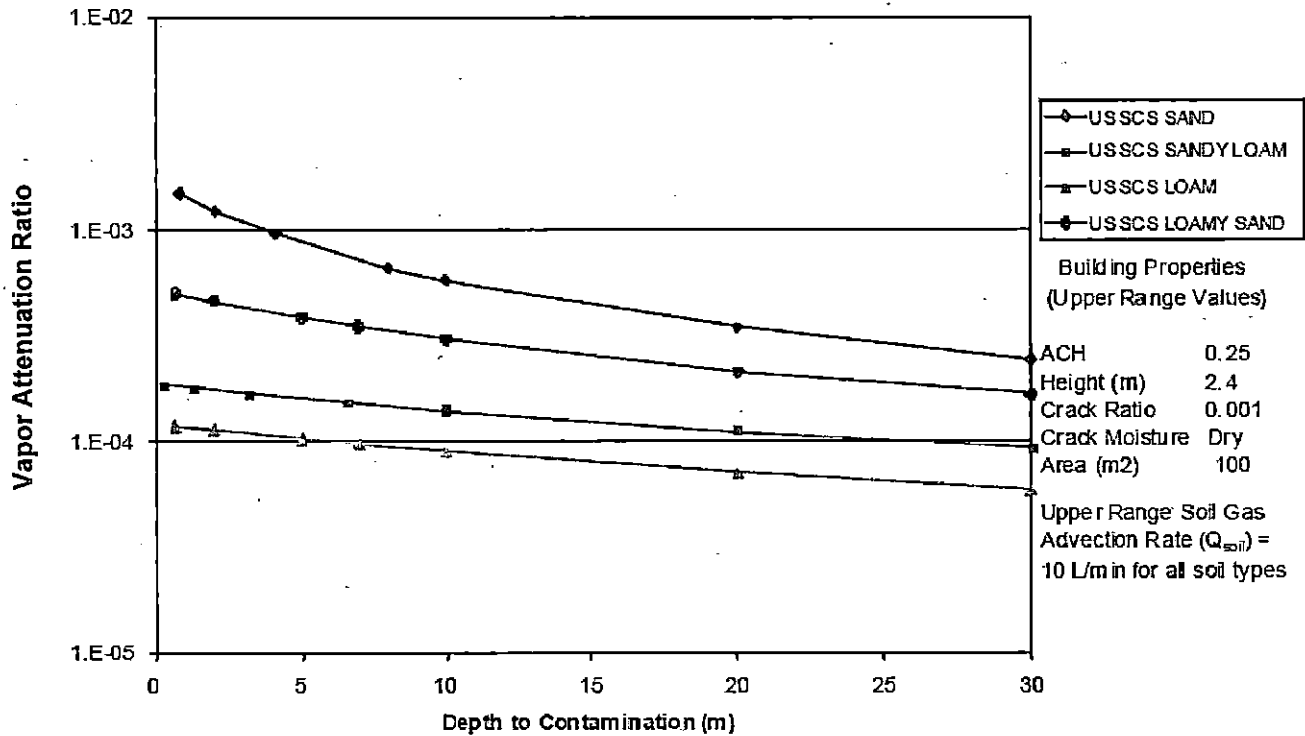


FIGURE 2

Graph 1b. For use with groundwater monitoring data.

(future edits to add: units of feet, ½ order-of-magnitude lines, and clarify y-axis is "Vapor Attenuation Ratio")

Rationale for Selecting Site-Specific Attenuation Factor and Reference(s):

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

### Site-Specific Assessment – Question 6

Q6: Do measured or reasonably estimated soil gas or ground water concentrations exceed media-specific criteria developed specifically for this site?

\_\_\_\_\_ If YES - check here and implement exposure controls (avoidance or mechanical systems with appropriate monitoring to demonstrate their effectiveness) to prevent possible human exposures to subsurface vapors migrating into indoor air. Prepare a performance monitoring plan and proceed to Question 7;

\_\_\_\_\_ If NO – check here and provide documentation of Site-Specific Assessment for regulatory review.

\_\_\_\_\_ If sufficient data are not available - check here and skip to Pathway-Specific EI Summary Page and enter “IN” (more information needed) status code.

#### Criteria:

The Site-Specific Pathway Assessment is intended to be used where site-specific conditions warrant further consideration prior to concluding either that the pathway is incomplete, or that some form of exposure control is required. The assessment could be as simple as using the same equations employed to develop the Secondary Screening criteria but with revised inputs that are defended with site-specific data. It could also be as complex as a comprehensive mapping of subsurface vapor distributions and measurement of subsurface material properties affecting gas flow and transport, combined with the development of a site-specific vapor transport model. The data needs are greater here than in the Primary and Secondary Screening; however, the necessary data might already be available from previous site characterization work. A conceptual model of the site and subsurface vapor transport and vapor intrusion mechanisms will be needed to defend the Site-Specific Pathway Assessment. Model inputs and assumptions that are different than the generic assumptions in Questions 4 and 5 criteria (and others to be added to the appendices) must be supported with site-specific data.

The site-specific conceptual model should be developed in the source-pathway-receptor framework, and it should identify how the site-specific conceptual model is similar to, and different from, the generic conceptual model used in developing Table 3. Key components of the conceptual model may need to be justified with site-specific data, including, but not limited to the source (chemical constituents, concentrations, mass, phase distribution, depth, and aerial extent), pathway (soil texture, moisture, and layering) and receptor (building design, construction, and ventilation). The indoor air concentrations may be simulated with a mathematical model, which the user must be prepared to document and defend as appropriate for the site-specific conceptual model. The user must also defend model inputs (different than those (to be added to) the appendices) by validated site-specific data. The discussion above in Appendix A concerning data sufficiency is also applicable here. Indoor air quality sampling and analysis is neither required, nor precluded; however, if indirect data (e.g. soil gas data) are to be used exclusive of indoor air quality data, the vapor attenuation factor must be assigned either using site-specific data (e.g. the building ventilation rate, pressure differentials, soil gas permeability), or using conservative assumptions. If the pathway is not judged to be incomplete during the Primary, Secondary, or Site-Specific Screening, it is considered to be complete, unless some action is taken. Possible actions include:

- engineered containment systems (subslab de-pressurization, soil vacuum extraction, vapor barriers)
- ventilation systems (building pressurization, indoor air purifiers)
- avoidance (temporary or permanent receptor relocation) or
- removal actions to reduce the mass and concentrations of subsurface chemicals to acceptable levels
- (i.e., remediation efforts).

## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

### **Rationale and Reference(s):**

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## EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

### Post-Assessment Monitoring – Question 7

Q7: Will temporal monitoring data or performance monitoring data (for a mechanical exposure control system) be collected to assess whether the pathway remains incomplete?

\_\_\_\_\_ If YES - check here and provide a brief summary of the monitoring requirements, or reference monitoring work plan.

\_\_\_\_\_ If NO – check here and provide justification.

#### Criteria:

**Performance Monitoring** is necessary to ensure that the pathway remains incomplete for sites relying on exposure control systems. **Pathway Monitoring** is recommended for sites where the measured or reasonably estimated media concentrations are at, or marginally less than the target media concentrations for that site, or when temporal trends cannot be reasonably predicted with existing data. This could involve repeated sampling of groundwater, soil gas, or indoor air on some appropriate frequency. The need for pathway monitoring is decided by the lead regulatory authority; however, one should consider the derivation of the target media concentrations and differences between those and measured or reasonably estimated values when determining monitoring requirements. Presumably, monitoring is less important in cases where measured or reasonably estimated media concentrations are an order of magnitude less than the more conservative media criteria (Table 2), and monitoring is more important when measured or reasonably estimated media concentrations are only marginally less than criteria selected at Question 5 (Table 3) or Question 6. As additional data becomes available, it should be compared with previous data as well as the target media-specific concentrations. If exceedances occur, or are projected to occur, appropriate actions (usually engineering controls) should be taken, or continued. If monitoring demonstrates that the pathway is incomplete and will remain so under current site conditions, then other actions are not necessary.

#### Rationale and Reference(s):

# EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY

## Pathway-Specific EI Summary Page

Facility Name: B. Braun Medical, Inc.

Facility Address: 901 Marcon Boulevard, Allentown, PA 18109

Facility EPA ID #: PAD982679169

Below, check the appropriate status codes for the Subsurface Vapor to Indoor Air Pathway evaluation on the EI determination and attach appropriate supporting documentation as well as a map of the facility.

### Is there a Complete Pathway for subsurface vapor intrusion to indoor air?

  X   NO – the "Subsurface Vapor Intrusion to Indoor Air Pathway" has been verified to be incomplete, based on review of the information contained in this EI Determination of the B. Braun Medical, Inc. facility, EPA ID # PAD982679169, based on performance monitoring evaluations for engineered exposure controls. This determination will be re-evaluated when the Agency/State becomes aware of any significant changes at the facility.

       YE – Yes, The "Subsurface Vapor to Indoor Air Pathway" is Complete.

       IN – More information is needed to make a determination.

### Locations where References may be found.

|                          |                            |
|--------------------------|----------------------------|
| USEPA Region III         | PADEP                      |
| Waste and Chemical Mgmt. | North East Regional Office |
| Division                 | 2 Public Square            |
| 1650 Arch Street         | Wilkes-Barre, PA 18701     |
| Philadelphia, PA 19103   |                            |

### Contact telephone and e-mail numbers:

(name) \_\_\_\_\_

(phone #) \_\_\_\_\_

(e-mail) \_\_\_\_\_

This document is dedicated to the late Craig Mann, who was a member of the authoring committee, a prominent researcher in the field and programmer of the widely-used spreadsheet version of the Johnson and Ettinger (1991) model available at [www.epa.gov/superfund/programs/risk/airmodel/johnson\\_ettinger.htm](http://www.epa.gov/superfund/programs/risk/airmodel/johnson_ettinger.htm). He was a friend and inspiration to us all.

FINAL NOTE: THE HUMAN EXPOSURES EI IS A QUALITATIVE SCREENING OF EXPOSURES AND THE DETERMINATIONS WITHIN THIS DOCUMENT SHOULD NOT BE USED AS THE SOLE BASIS FOR RESTRICTING THE SCOPE OF MORE DETAILED (E.G., SITE-SPECIFIC) ASSESSMENTS OF RISK.